

**AUG 1 8 2000**

Xia Spine System Sacral Block Assembly

510(k) Premarket Notification

K 001653

**Summary of Safety and Effectiveness for the  
Xia Spine System Sacral Block Assembly**

**Submission Information**

**Name and Address of the Sponsor  
of the 510(k) Submission:**

Howmedica Osteonics Corp.  
59 Route 17  
Allendale, NJ 07401-1677

**Contact Person:**

Mary-Catherine Dillon  
Regulatory Affairs Specialist

**Date of Summary Preparation:**

May 25, 2000

**Device Identification**

**Proprietary Name:**

Xia Spine System

**Common Name:**

Spinal Fixation Appliances

**Classification Name and Reference:**

21 CFR 888.3050

**Device Description**

The Xia Spine System Sacral Block Assembly consists of a Xia Sacral Block with set screw and a 6.5 mm diameter Xia bone screw. The Sacral Block connects the 6.5 mm diameter bone screw to the Xia Spinal System rod and features a pocket for the bone screw and an inner bore for the spinal rod. The Sacral Block is placed on the spinal rod, and the set screw is tightened to lock

the Sacral Block to the rod. The 6.5 mm diameter Bone Screw, which is offered in lengths from 25 to 60 mm in 5-mm increments, is placed in the bone through the hole in the Sacral Block.

The Xia Spinal System Sacral Block Assembly components are fabricated from ASTM F-136 Ti6Al4V ELI Alloy.

**Indications:**

The Xia Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the Xia Spinal System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the Xia Spine System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (psuedoarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the Xia Spine System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, psuedoarthrosis or revision of failed fusion attempts.

**Performance Data:**

Testing has been conducted to demonstrate the substantial equivalence of this system to other legally marketed systems in terms of mechanical strength.

**Statement of Technological Comparison:**

The substantial equivalence of this device is based on equivalence of intended use, materials, design and operational principles to other predicate devices intended for noncervical spinal fixation. These devices include the Osteonics® Spinal System Sacral Offset Connector Assembly by Howmedica Osteonics Corp., Sofamor Danek's Tacoma™ Sacral Plate System and the Saddle with Anchor™ Fixation System by Advanced Spine Fixation Systems, Inc. Mechanical testing and Finite Element Analysis demonstrate that the device meets the mechanical functional requirements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 18 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Elizabeth A. Staub  
V.P. – Quality Assurance/ Regulatory Affairs/ Clinical Research  
Stryker Howmedica Osteonics  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K001653

Trade Name: Xia Spine System Sacral Block Assembly  
Regulatory Class: II  
Product Code: KWP, KWQ, MNI, and MNH  
Dated: May 26, 2000  
Received: May 30, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

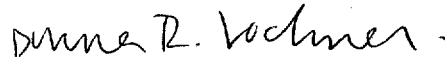
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.


This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Ms. Elizabeth A. Staub

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K001653Device Name: Xia Sacral Block Assembly, Xia Spine System

The Xia Sacral Block Assembly is intended to be used as part of the Xia Spine System.

## Indications For Use:

The XIA Spine System is intended for use in the noncervical spine. When used as a pedicle screw fixation system, the XIA Spine System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

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When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the XIA Spine System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE) -----

Dan R. Lockner  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K001653

Prescription Use X

OR

Over-The-Counter Use \_\_\_\_\_ (Per 21 CFR 801.109)  
(Optional Format 1-2-96)